



TECHNICAL UPDATE

Sterilization Method

12/13/05

Introduction

This document describes the radiation sterilization procedures and packaging for pre-sterilized products manufactured by Continental Laboratory Products.

Sterilization Method

Because all types of ionizing radiation used for sterilization have deleterious effects on plastic product performance and appearance, CLP continuously explores ways to reduce radiation dosage levels. Most manufactures use gamma radiation for sterilization, but studies have shown that beta (electron-beam) radiation demonstrates less product damage, while being just as effective for sterilization. CLP has always, and will continue to use beta radiation for all product sterilization.

Continuous Bio Load Testing

Bio load is the amount of microorganisms and other organic materials such as endotoxins and nucleases contaminating a product. CLP continually monitors the bio load of product, both before and after sterilization. For a complete description of testing procedures, please see CLP document: "Current Certification Standards".

Low Initial Bio Load results in less radiation.

Through continual improvement in our production processes, CLP has been able to essentially eliminate bio contamination of plastic products during production and packaging, as demonstrated by our bio load testing program. This lower initial bio load level reduces the radiation required for complete sterilization and bio molecule inactivation. Please see CLP document: "Current Sterilization Procedures".

Radiation Indicator Labels

All radiation indicator labels (radiation dots) are designed for use with gamma radiation, but will reliably react to high dose beta radiation dosages. At the low dose beta radiation levels CLP currently requires for sterilization, indicator label color change is unreliable. CLP has discontinued the use of radiation indicator labels on all sterile products.

Sterile Product Packaging Changes

Because low dose beta radiation indicator labels are not commercially available, CLP is revising its sterilization and packaging procedures to eliminate indicator dot labels. To assure product quality, CLP will continue to monitor production process bio load and lot test all sterilized products for post sterilization bio load elimination. Please be assured that all sterile products have been properly processed and tested.

Certification

These processing and packaging procedures will provide increased performance and reliability of sterile plastic products from CLP. For your protection, a continuous record of product testing and certification is maintained by the CLP Quality Assurance Department. For questions, please contact CLP customer service with the control lot number of your CLP sterile product.